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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,289	01/05/2004	Steven M. Watkins	475512000100	1703
25226	7590	06/29/2006	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			NEGIN, RUSSELL SCOTT	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,289	WATKINS, STEVEN M.	
	Examiner	Art Unit	
	Russell S. Negin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44, 47 and 49-53 is/are pending in the application.
- 4a) Of the above claim(s) 45, 46 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44, 47 and 49-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Notes

Claims 45, 46, and 48 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 45, 46, and 48 depend from a non-existent claim 60 and thus fail to distinctly and comprehensively claim subject matter. They will not be classified or treated on the merits in the following restriction requirement and specie election.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a method for presenting analyses of a plurality of individual quantitative metabolite profiles, classified in class 702, subclass 19. If this group is chosen, the below mentioned species election(s) are also required.
- II. Claims 20-38, drawn to a method for determining a metabolic effect of a condition, classified in class 702, subclass 19. If this group is chosen, the below mentioned species election(s) are also required.
- III. Claims 40-43, 44, 47, drawn to a method of analyses of lipids that are related to disease, classified in classes 702 and 514, subclasses 19 and

1, respectively. If this group is chosen, the below mentioned species election(s) are also required.

- IV. Claims 49-53, drawn to a database with specific features and tables in gathering data in biological samples, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and [I – III] are directed to related apparatus and process. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Invention IV claims a type of database to a significant level of detail that is not employed in the other Inventions. For example, the profile table, the sample item table, the condition item table, and the filter item table are tables only employed in Invention IV. Searching this database and the methods of Inventions I, II and/or III would provide undue burden because of their divergent subject matter.

Inventions I and [II and III] are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Invention I does not have the requirement that the method be executed concerning a particular condition or disease. Searching such an Invention in

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combination with an Invention that requires data for a specific disease would be undue burden.

Inventions II and III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while Invention II is determination of a metabolic effect of a condition, Invention III involves treating, reducing, or preventing a disease or progression of a disease. It would be undue burden to search both types of approaches towards addressing diseases.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Elections for Invention I:

If Invention I is chosen, the following five (5) species elections are required. Applicant must pick a single specie from each of the five categories.

Category #1: Lipid metabolites (claim 4 and 14)

Applicant must pick a combination of at least two lipids from the group listed in claim 4.

Each lipid is a physically different molecule with its own physical properties.

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Category #2: fatty acids (claim 7)

Applicant must pick one acid from among the fatty acids listed in claim 7.

Each fatty acid is a physically distinct molecule with its own set of properties.

Category #3: lipids that are sterols (claim 8)

Applicant must select one sterol from the list displayed in claim 8.

Each sterol is a physically distinct molecule with a unique set of physical properties.

Category #4: lipid classes (claim 9 and 13)

Applicant must select from among the lipid classes listed in claim 9.

Each lipid class is comprised lipids that are physically distinct with their own set of physical properties.

Category #5: internal standard (claim 10)

Applicant must select from among the internal standards listed in claim 10.

Each internal standard is physically distinct with its own set of physical properties.

Species Elections for Invention II:

If Invention II is chosen, the following one (1) species elections are required.

Applicant must pick a single specie from the category.

Category #1: condition type (claims 23-26)

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Specie A: the condition comprises a dietary limitation or supplementation (claim 23)

Specie B: the condition comprises a disease or disease state (claim 24)

Specie C: the condition comprises application of a toxin or suspected toxin (claim 25)

Specie D: the condition comprises application of a pharmaceutical agent or candidate agent (claim 26)

Justification: Each type of condition of a physically different event in addressing the disease.

Species Elections for Invention III:

If Invention II is chosen, the following two (2) species elections are required.

Applicant must pick a single specie from each of the two categories.

Category #1: disease status (claim 42)

Applicant must choose a method of using a quantitative lipomic database in disease diagnosis, prognosis, or prediction.

Diagnosis, prognosis, or prediction are independent events in addressing diseases.

Category #2: method of screening (claim 44)

Applicant must choose if a method of screening for a compound is useful for treating, reducing, or preventing a disease or a progression of a disease.

Treating, reducing or preventing a disease are independent events in screening for a compound.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19 are generic for Group I, claims 20-22, 27-38 are generic for Group II, and claims 40-43 and 47 are generic for Group III.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Andrew Wang, Supervisory Patent Examiner, can be reached at (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

-RSN June 22, 2006

John S. Brusca 22 June 2006

John S. Brusca 23 June 2006
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER